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| 09/641,034 | 08/16/2000 | Toshiyuki Yoneda | BEAR-006 | 3757 |

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| EXAMINER | |
|---|---|
| MAYES, LAURIE A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1653 | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/641,034 | Applicant(s) YONEDA ET AL. | |
|---|---|---|---|
| | Examiner Laurie Mayes | Art Unit 1653 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *27 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-9 and 12-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5 & 7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

The applicant's response received on December 27, 2002 has been entered. Applicant's election with traverse of group I, claims 1-9 and 12-16, in Paper No. 12 is acknowledged. The traversal is on the ground(s) that it would not be unduly burdensome to perform a search for all of the claims together. This is not found persuasive because the antibodies in claims 10 and 11 are structurally different chemical compounds from the proteins and have different functions and uses. It would be burdensome to the examiner to perform additional searches on these structurally different antibodies. Further, claim 6 does not contain the sequence elected by the applicant, SEQ ID NO:47. Rather, claim 6 relates to a different invention than the claims consisting of elected SEQ ID NO: 47 as it contains many different sequences corresponding to structurally different chemical compositions than SEQ ID NO:47. The peptides of claim 6 do not contain a peptide with SEQ ID NO: 47. Thus, claim 6 is treated as a non-elected invention. **Therefore, claims 1-5, 7-9 and 12-16 will be examined and claims 6, 10 and 11 are considered non-elected claims and will not be examined.** The requirement is still deemed proper and is therefore made FINAL.

### *Specification*

Claims 6, 7 and 9 are objected to as they contain sequences more than four amino acids in length and fail to recite "SEQ ID NO: ___". See 37 CFR 1.821-1.825. Also, these sequences are not identified by a SEQ ID NO: in the body of the specification.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language "substantially the same" in claim 8 is unclear because it is subject to more than one interpretation as follows:

(a) does it mean varying numbers and kinds of insertions, substitutions, deletions and combinations of one or more amino acids thereof? If so, these must be specified. Or,

(b) does it mean modified side chains of amino acids such as beta or gamma and/ or delta amino acids?

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 7-9, 12 and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 99/60017 (cited in IDS, paper # 7). WO 99/60017 teaches a protein (SEQ ID NO:2) comprising an amino acid sequence identical to SEQ ID NO:47 (recited in claim 7 and anticipatory to claim 1) in the present application (see the attached sequence alignment) which is comprised of about 10 to 50 amino acids, the integrin binding motif, RGD, and biological activity which enhances bone growth (p.1, last para. and claims 24, 39 and 40) and wherein the amino acids are in the L-conformation (absent disclosure of D-configuration, they would have been expected to have been in the L-configuration), where the amino acid sequence is contiguous

with the RGD sequence in naturally occurring protein matrix extracellular phospohglycoprotein (human protein—see abstract and p. 4 of the sequence listing), where the peptide is biologically active in promoting phosphate metabolism and bone growth (claim 24, 39 and 40; the phosphatonin polypeptide positively regulates bone mineralization which is a pre-requisite for bone growth, p. 43, lines 1-3 and p. 49, lines 22-26) and may be used to treat impaired bone formation and osteomalacia (p. 49, lines 10-11) and wherein the peptide is administered in a formulation comprising a therapeutically effective amount with a carrier (claims 24 and 32). WO 99/60017 teaches all of the elements of claims 1-5, 7-9 and 12 and thus these claims are anticipated under 35 U.S.C. 102 (a).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 7-9 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reynolds (United States Patent Number 5,015,628) in view of WO 99/60017 and Kumagai et al. (United States Patent Number 5,837,674). Reynolds teaches the use of phosphopeptides, similar to those in the present invention, which also are biologically active in promoting bone growth (col. 1, lines 26-35) and may be used to treat osteomalacia (col. 1, lines 31-32) in addition to treating the teeth by administering a mouthwash (Ex. 17) or toothpaste (Ex. 11) comprising phosphopeptides. Reynolds does not teach such a formulation wherein the carrier is a saline solution and the formulation is injectable, wherein the carrier is paste and the formulation is a toothpaste, or wherein the carrier is an aqueous flavored solution and the formulation is a mouthwash.

WO 99/60017 teaches a peptide comprised of ten to 50 amino acids, an RGD sequence, amino acids substantially the same as those contiguous with an RGD sequence of naturally occurring matrix extracellular phosphoglycoprotein and which is biologically active in promoting bone growth (p.1, last para. and claims 24, 39 and 40) and that is administered in a formulation comprising a therapeutically effective amount with a carrier to treat osteomalacia in mammals (claim 38) and related phosphate-related disorders. WO 99/60017 does not teach such a formulation is a toothpaste or mouthwash or the carrier is saline. Kumagai et al. teach the use of phosphopeptides, similar to those in the present invention, which also are biologically active in promoting bone growth (Fig. 5) and may be used to treat osteomalacia (col. 11, line 18) and other related diseases and may be administered in a pharmaceutically effective amount by a saline formulation (Figs. 3-7) that is injectable (col. 10, lines 15-23) to enter the systemic

circulation (col. 10, line 25). Kumagai et al. do not teach a formulation that is a toothpaste or mouthwash.

As Reynolds teaches the use of phosphopeptides in a mouthwash or toothpaste to treat the teeth and also the use of phosphopeptides to promote bone growth and treat osteomalacia, as WO 99/60017 teaches the advantages of administering a peptide comprised of an RGD sequence of naturally occurring matrix extracellular phosphoglycoprotein, in a carrier, to promote bone growth, and as Kumagai et al. teach the advantages of injection of a formulation comprising a phosphopeptide and carrier to promote bone growth, it would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to administer the phosphopeptide as claimed in the present invention in a mouthwash, toothpaste or in saline to treat and maintain the teeth and bones in mammals or to administer it by injection with a pharmaceutically acceptable carrier in a therapeutically effective amount to enhance bone growth.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 7 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 305-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

L. Mayes

Laurie Mayes
Patent Examiner
Art Unit 1653
February 14, 2003

Christopher S. F. Low

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